

Press Release

Frauenfeld, Switzerland – February 2nd, 2023

SIS Medical AG announces the US-launch and the first US-treatment with the Super-High-Pressure balloon – OPN NC[®] – with TWIN-Wall technology

SIS Medical AG (Swiss Interventional Systems), a globally leading developer, manufacturer and distributor of high-quality and high-performance products in the field of interventional cardiology, announces the launch of its lead product **OPN NC[®] PTCA Dilatation Catheter with TWIN-Wall technology** in the US. The product extends treatment options by high performance and safety as well as providing success rates where other balloons fail. It is distributed by Worldwide Innovations & Technologies, Inc. (manufacturer and distributor of RADPAD[®] Radiation Protection Products), which is headquartered in Lenexa, Kansas.

The OPN NC[®] catheter has a unique TWIN-Wall design, invented at SIS Medical AG, providing a super high pressure resistance with a rated burst pressure of 35 atm with a very low compliance. These performance features allow for a perfect preparation of challenging lesions prior to stenting without over-dilating of the blood vessel. The device can also be applied for post-dilatation of under-expanded stents. OPN NC[®] coronary balloon is the only Super-High-Pressure coronary balloon rated with 35 atm which received the 510(k) clearance by the U.S. Food & Drug Administration (cleared under the number K212393 in March 2022).

The first US treatment took place in the Morristown Medical Center in New Jersey by Interventional Cardiologist, Dr. Philippe Genereux. “I was extremely satisfied with the performance of the OPN NC[®] balloon. We were successful in efficiently treating multiple patients with very complex and calcified lesions. The OPN NC[®] balloon is an essential tool for operators treating resistant lesions, restenosis, or to treat acutely under-expanded stent, and is a true cost-effective technology compared to other devices.”

“Our OPN NC[®] balloon with TWIN-Wall technology has already been successfully used for several years in Europe and other countries. More than 140,000 patients have been treated with the product so far. With the US launch, our company has reached yet another significant milestone. The first cases at the Morristown Medical Center have shown a strong need for our technology to improve the treatment of challenging coronary lesions in US patients. Many other US hospitals will be introducing the OPN NC[®] within the next few weeks”, says Sergej Kammerzell, CEO of SIS Medical AG.

“Access to the US market will have a great impact on the further development, reputation, and continued international growth of SIS Medical AG”, adds Willi Zwahlen, VP Sales & Marketing, Founder and Board Member of SIS Medical AG. “The US launch is a key-element of our strategy to make OPN NC[®] available in all major global markets.”

Eric Radtke, Vice President Sales & Marketing at RADPAD, further concludes: “OPN NC[®] is an exciting product that we can provide to a wide customer base in the US. We look forward to adding value to our customer facilities by delivering another high-quality, life saving device.”

John Cadwalader, CEO at RADPAD, states: "We are excited to be the U.S. distributor for OPN NC® and look forward to being a part of providing a major step forward in interventional medicine in the US."

About SIS Medical AG

SIS Medical AG, based in Frauenfeld, Switzerland, is a leading Swiss developer, manufacturer, and distributor of high-quality and high-performance PTCA balloons. The company is very well known in the field of interventional cardiology for its lead product **OPN NC® Super High-Pressure PTCA Balloon with TWIN-Wall technology** which allows the treatment of challenging coronary lesions and the optimization of the stent results.

<https://www.sis-medical.com/>

About Worldwide Innovations & Technologies, Inc. (RADPAD)

Worldwide Innovations & Technologies, Inc. (WIT), headquartered in Lenexa, Kansas, was founded in July 1992 with the purpose of developing and marketing radiation protection products which are widely used in the coronary catheter labs. RADPAD® emerged from WIT's developmental years. RADPAD® products are sterile and lead free. They are completely disposable and create no environmental issues.

<https://radpad.com/about-us/>

Press Contact

IWK Communication Partner

Stefan Eberherr

t.: +49 89 2000 30-32

stefan.eberherr@iwk-cp.com